

R E M A R K S

Claims 16-18, and 23-37 are pending in this application. Claim 8 has been cancelled, claims 16, 17, 23, 24, 27, 29 and 31 have been amended and claims 33-37 are newly added. No new matter has been added by way of the present amendments. For instance, claims 23 and 24 have been amended to recite "a therapeutically effective amount of" and to define the one or more symptoms accompanying diminished homeostasis as being "associated with premenstrual syndrome." The Examiner is referred to the present specification at page 1, lines 9-11, and page 8, line 14 to page 9, line 4. Additionally, the recitation of "autism" as been removed from claims 23 and 24. The dependencies of claims 16, 17, 27, 29 and 32 have been altered as necessitated by the cancellation of claim 8. New claims 33-37 are supported by pending claims 16-18, 25 and 26, respectively, as well as the present specification at page 6, line 14 to page 7, line 5, page 8, lines 14-22 and page 13, line 20 to page 14, line 3. Accordingly, no new matter has been added.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw all the rejections and allow the currently pending claims.

Issues under 35 U.S.C. § 112, first paragraph

The Examiner has rejected claims 8, 16-18 and 23-32 under 35 U.S.C. § 112, first paragraph for the reasons recited at page 2 of the outstanding Office Action. In particular, the Examiner asserts that the specification does not provide proper written description for treating patients with the specifically named symptoms, but not associated with premenstrual syndrome.

Applicants respectfully traverse this rejection. The claims have been amended so that the symptoms are defined as being associated with premenstrual syndrome. Accordingly, this rejection is moot. Reconsideration and withdrawal thereof are respectfully requested.

Issues under 35 U.S.C. 103(a)

The Examiner has rejected claims 8, 16-18 and 21-32 as being obvious over Fuji et al., JP 406100442 (hereinafter referred to as Fuji '442) in view of the Merck Manual (fifteenth edition). Applicants respectfully traverse this rejection.

As a preliminary note, claims 21 and 22 have been cancelled and thus have been improperly rejected.

Regardless, Applicants submit that the presently pending claims are patentable over the cited art. The cited art fails as a whole to disclose the use of either isolated or purified

theanine for suppressing or ameliorating one or more of the cited symptoms associated with premenstrual syndrome. The fact that Fuji '442 may disclose an anti-stress composition is irrelevant since there is no motivation to use such a composition to suppress or ameliorate one or more symptoms associated with a premenstrual syndrome (PMS) patient.

Applicants note that the present claims relate to suppressing or ameliorating one or more symptoms associated with PMS in an individual. The symptoms are specifically recited in the independent claims and include sleepiness, fatigability, stiff breasts, painful breasts, likelihood to have acne, chapped skin, bad spread of cosmetics, increased vaginal discharge, inability to take smooth body action, allergic symptoms, headache, head stuffiness, stiff shoulders, vertigo, limb coldness, abdominal pain, lower abdominal pain, lower abdominal stiffness, lumbago, swelling, thirst, constipation, diarrhea, food preference change, spiritlessness, aggressiveness, faintheartedness, maudlinness, solitariness, loneliness, psychological lift, increased sexual desire, mysophobia, inability to manage one's health, repugnance to menstruation, repugnance to being female, craving to be alone and unsociableness.

The above listed symptoms, although associated with PMS, do not include stress. In this manner, the present claims do not involve the treatment of stress. Based upon the present claims, Applicants respectfully submit that the prior art fails to suggest or disclose the use of isolated or purified theanine as currently claimed for suppressing or ameliorating one or more of these symptoms. Accordingly, the Examiner has failed to present a valid *prima facie* case of obviousness.

In summary, Applicants submit that the present claims are in condition for allowance. Therefore, the Examiner is requested to withdraw all rejections and allow the currently pending claims.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Craig McRobbie (Reg. No. 42,874) at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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